

PSJ14 Janssen Opp Exh 61 – JAN-MS-03124101

Work Instruction

Owner Group: CLS-JOM	Effective Date: 24-Jul-2013 10:30:41 EDT
Document Title: JOM Customer Service Suspicious or Excessive Orders	
Document Number: DS-WI-3824	Version: 2.0

1.0 Purpose

- 1.1 To define a process that complies with DEA or state requirements to provide information on any prescription order (controlled or non-controlled substances) that could be considered potentially suspicious or excessive.

2.0 Scope

- 2.1 The scope of this work instruction is to identify, track, and report suspicious or excessive controlled substance and non-controlled substance prescription orders. This includes prescription products that may be scheduled under state, but not federal law.

3.0 Definitions

- 3.1 Use DS-WI-3795, *Customer Service Definition Document*.
- 3.2 A potentially suspicious or excessive controlled substance order can be defined as an order that exceeds the minimum order quantity requirements, and is above 3xs (300% of) the calculated, 12 month, per weekly order average. (This definition also applies to products that are scheduled in one or more states, but not by the DEA.)
- 3.3 A suspicious non-controlled substance prescription product order is an order that a Channel Operations or CSS Team member has reason to believe is being placed for illicit purposes.
- 3.4 ValueTrak – A database containing customer order demand history.

4.0 Responsibilities

- 4.1 It is the responsibility of the Schedule II Team member to follow this work instruction for identifying potentially suspicious or excessive controlled substance orders.
- 4.2 It is the responsibility of the Channel Operations Analyst or CSS (Customer Support Services) member to follow this work instruction for identifying potentially suspicious or excessive non-controlled prescription product orders.
- 4.3 It is the responsibility of the CSS Team Leader to ensure this work instruction is followed.

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4.4 It is the responsibility of the DEA Compliance Team to review and determine the decision to ship any order identified by this process and to report any potentially suspicious or excessive orders to the DEA and/or appropriate state or federal regulatory agency.

4.5 It is the responsibility of the CSS Member to ensure all Schedule II products remain on hold until they are reviewed for suspicious and excessive ordering.

4.6 It is the responsibility of DEA Compliance to respond in a timely fashion.

5.0 Safety and Environmental Practices

5.1 N/A

6.0 Equipment/Materials

6.1 SAP R/3 Order Processing Database

6.2 Business Warehouse Reports

6.3 ValueTrak

7.0 Instructions

7.1 Monitoring DEA Controlled Substances Orders

7.1.1 To run the daily "DEA Unusual Order Quantity Report"



Please note that the "DEA Unusual Order Quantity Report" must be ran daily at the end of each day. Run must be completed prior to releasing narcotic orders.

7.1.1.1 Open SAP Log-in Pad

7.1.1.2 Double Click on "BPV (BW Prod)" to open SAP Business Warehouse

7.1.1.3 Log-in using WWID and Password.

7.1.1.4 Type in transaction SM37 in transaction field and press enter.

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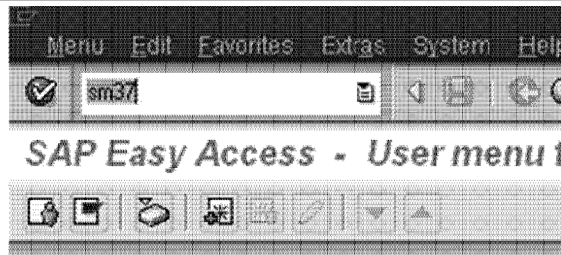
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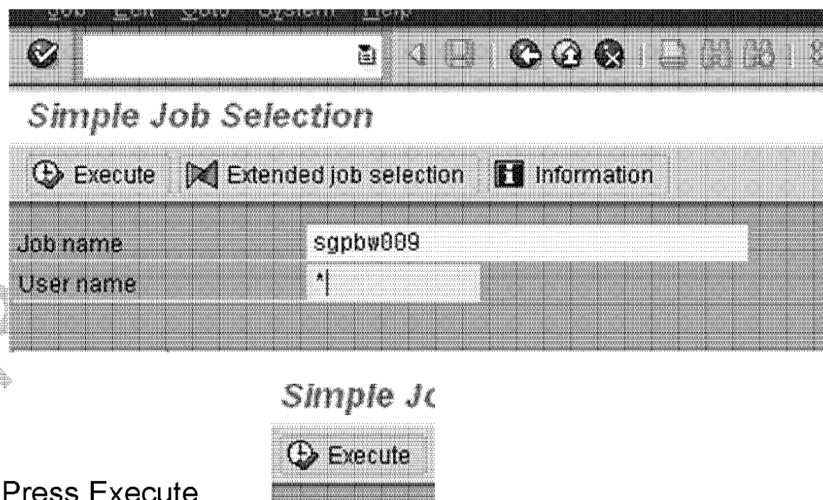
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7.1.1.5 In the Job name field type in sgpbw009

7.1.1.6 In the User name field type in *



7.1.1.7 Press Execute

7.1.1.8 Check Status of the Job Overview to make sure it states FINISHED.

Job	Spool	Job Doc	Job Created	Status	Start date	Start time	Duration(sec.)	Delay (sec.)
SGPBW009			STONEBRANCH	Finished	05/08/2013	06:32:37	2,700	0
*Summary							2,700	0

7.1.1.9 If Status shows finished, proceed with the next steps. If the this step is not complete, no product can be released until report has a FINISHED STATUS.

7.1.1.10 Green arrow back twice.

7.1.1.11 Open "DEA Unusual Order Quantity Report" query.

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The query will open with the previous day's date and current day's date automatically populated in the date range. When processing the report on the first business day of a new week, overwrite the previous day's date with the previous business days date.

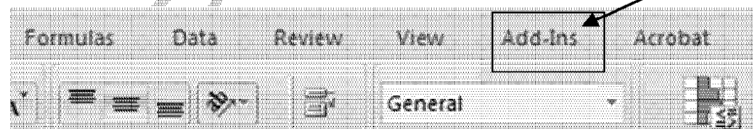
(i.e.: On Monday's report, use Fridays date as the starting point.)

7.1.1.12 Type in 0100 in the Sales Organization Section.

7.1.1.13 Execute the report by clicking on the execute button.



7.1.1.14 Once report generates click on the Add Ins tab at the top of the excel sheet



7.1.1.15 Click on the Business Explorer icon.



7.1.1.16 Click on Display Text Elements. → All

7.1.2 The report will run and return results of any Narcotic orders (Schedule II – V) for which the order quantity is greater than or equal to 3 x (300% of) the calculated, 12 month, per order average.

7.1.3 All Schedule II – III orders not on hold as part of Suspicious or Excessive Orders (orders not appearing in the report) may be released with a Channel Operations Analyst or designated CSS member.

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7.1.4 All Schedule II - III orders that are viewed as potentially suspicious or excessive including customers who have not ordered in the past 12 months (orders appearing in the report) will continue to be held and the customer will be contacted by a Schedule II Team Member. Schedule II team will put the order on "Customer Service Review" and will request an explanation for the increased demand and change in order pattern (more than one order processed per product per week).

7.1.5 CSS is to adhere to the following script when contacting the customer:

7.1.5.1 "JOM is committed to complying with all DEA guidelines and regulations. Part of that commitment requires us to identify suspicious or excessive orders and notify the DEA accordingly. We have noticed this week's order has exceeded your normal demand. "

7.1.5.2 What is the name of your customers you are supplying?

7.1.5.3 What city and state are they in?

7.1.5.4 Has this customer had any suspicious or excessive orders in the last 12 months?

7.1.5.5 If yes, which product/products?



Schedule II Team member will alert Channel Operations analyst or designated CSS member to continue to hold order if customers response is not received within 48 hrs.

7.1.6 Once the reason for the increase is received, then Schedule II Team member will run a Valuetrak report that will show the customers inventory and compare to the demand of the increase.

7.1.7 The Schedule II Team Member will forward customers order information, customer response for the increase using the JOM Customer Service Suspicious & Excessive Form and Valuetrak spreadsheet to DEA Compliance for further review.

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JOM Customer Service Suspicious & Excessive

Customer Information		Enter all information in this column.	
Ship to Loc #:	10745		
Ship to Name & Address:	Amertec Corp Bergen		
	212 Amy Rd		
	Somerset, NJ 07852		
Order #:	42596310		
PO #:	0485269		
Order Date:	04/21/2015		
CRM #:	RWA0325948		
222 Form #:	012552689		
When the customer is (if any):			
Product Information			
N/A # (1):	044506105		
Product Name(s):	Orange 25 mg		
Quantity Ordered on PO:	144		
Batch # (s) (if any):	C14578		
Previous Suspicious orders to this location			
Yes/No:	no		
Product Name (s):	N/A		
Product Name (s):	N/A		
Date of previous S/S order(s):	N/A		
JOM Customer Service Contact			
Notes Completed by:	James A. Inverett		
Date Completed:	5/29/2012		

Additional Questions:

What is the name of your customer you are supplying?

What city and state are they in?

Has this customer had any suspicious or excessive orders in the last 12 months?

If yes, which product/products?



JOM Customer Service Suspicious & Excessive Sharepoint link:
<http://teamsna.jnj.com/psq/scheduleii/JOM%20Customer%20Service%20Suspicious%20%20Excessive%20Form/Forms/AllItems.aspx>

7.1.8 DEA Compliance will use the data provided and the customer communication to determine if the request for the order quantity is substantiated.



Should the customer refuse to provide an explanation for the increase in demand, the Schedule II Team Member will explain to the customer that the order cannot be shipped unless clearance is received from a DEA Compliance Representative.

7.1.9 Once DEA Compliance reviews the information, they will notify a Schedule II Team member if order may be released to ship or advise to inform customer that quantities need to be reduced.

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This worksheet will be saved in the Schedule II Team Sharepoint site, when order detail is present.

The URL for the file is:

<http://teamsna.inj.com/psg/scheduleii/Schedule%20II%20Suspicious%20and%20Excessive%20Order/Forms/AllItems.aspx> The DEA Unusual Order Quantity Report will be saved for a period of (2) two years on the Sharepoint site.



At this point, all controlled substance orders up to and including the last order reviewed may be released with the Channel Operations analyst or designated CSS member.

DEA Compliance will determine which orders, if any, need to be reported to the DEA and any other appropriate state or federal agency.

7.2 Monitoring Orders for products that are not scheduled by the DEA, but are scheduled by one or more state, (e.g. Tramadol based products)

- 7.2.1 The Channel Operations analyst or designated CSS member will follow the appropriate sections of reference DS-SOP-949, *JOM Customer Service Administration of the JOM Direct Purchasing and Distribution Policy (DPDP)* to monitor all orders for the designated products and flag orders that are considered based on a 12 month rolling average.
- 7.2.2 All orders that are viewed as potentially suspicious or excessive (orders appearing in the DPDP report) will continue to be held and the customer will be contacted by a Schedule II team member and/or Channel Operations Planner to request an explanation for the increased demand.
- 7.2.3 The Schedule II Team member will forward customers order information, customer response for increase using the JOM Customer Service Suspicious & Excessive Form and Valuetrak spreadsheet to DEA Compliance for further review.
- 7.2.4 DEA Compliance will use the data provided and the customer communication to determine if the request for the order quantity is substantiated. DEA Compliance will notify Schedule II Team Member of their determination.

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Should the customer refuse to provide an explanation for the increase in demand, the Schedule II Team Member will explain to the customer that the order cannot be shipped unless clearance is received from DEA Compliance.

- 7.2.5 Once DEA Compliance reviews the information, they will notify a Schedule II Team member if the order may be released to ship or advise them to inform the customer that quantities need to be reduced.



The DPDP worksheet will be saved in the Sharepoint site when order detail is present.

The URL for the file is:

<http://teamsna.inj.com/psq/channelops/Managing%20Business/Forms/AllItems.aspx?RootFolder=%2fpsq%2fchannelops%2fManaging%20Business%2fDPDP&FolderCTID=%7b51A9E654%2dA6D5%2d48E6%2d998A%2dF50BCB4A450A%7d>

The DPDP Unusual Order Quantity Report will be saved for a period of (2) two years on the Sharepoint site.



At this point, all orders up to and including the last order reviewed may be released with the Channel Operations Analyst or designated CSS member.

DEA Compliance will determine which orders, if any, need to be reported to the appropriate state or federal agency.

8.0 Content Reference

- 8.1 DS-SOP-949, *JOM Customer Service Administration of the JOM Direct Purchasing and Distribution Policy (DPDP)*.

9.0 Attachments

- 9.1 N/A

END OF DOCUMENT

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Version Number	Section	Description of Change
2.0	All	Entire document was rewritten to align with the current process.
2.0	All	Reformatted for Docspace and updated content references to Docspace document numbers.
1.0	All	This document was migrated effective from OneSource to Docspace with the legacy document number PSGA-DOC-45016 . Refer to the "JSC Document Management System Consolidation Change Request" (ESCC - 49149)

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Approver Name	Justification	Date
Guy Bacco	Department Approval	01-Jul-2013 10:20:49 EDT
Michael Levitt	Department Approval	01-Jul-2013 11:04:27 EDT
James Garboski	Quality Approval	16-Jul-2013 10:05:31 EDT

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